IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBOTT DIABETES CARE, INC., a Delaware corporation, Plaintiff, v. DEXCOM, INC., a Delaware corporation, Defendant.	)	C. A. No. 05-590 (GMS)

ABBOTT'S MOTION FOR LIMITED JURISDICTIONAL DISCOVERY AND FOR A CORRESPONDING EXTENSION OF THE BRIEFING SCHEDULE ON DEXCOM'S MOTION TO DISMISS

Abbott Diabetes Care, Inc. ("Abbott") respectfully requests a brief adjournment of the briefing schedule on DexCom's motion to dismiss in order to conduct limited discovery on the jurisdictional issues raised by that motion. Abbott filed this patent infringement action on August 11, 2005. On August 31, DexCom filed a motion to dismiss arguing, in part, that this Court lacks jurisdiction over Count I of Abbott's complaint, which seeks declaratory relief holding that DexCom's soon-to-be approved product will infringe Abbott's patents (D.I. 5, 6).

For its jurisdictional argument under Rule 12(b)(1), DexCom argues that Count I is "premature" based on the allegations that (1) DexCom's STS system "may never be approved" by the FDA or (2) "may not be approved in its current form." DexCom's Op. Br. at 1. In support of those allegations, DexCom relies on an affidavit from an employee (D.I. 8) and nine voluminous exhibits, which total over 400 pages (D.I. 7). DexCom's brief and affidavit also contain many factual allegations, including allegations relating to recent communications with the FDA, which DexCom did not describe in any detail. (DexCom's Op. Brief at 12).

Even though it supported its Rule 12(b)(1) motion with an affidavit and exhibits, DexCom declined, this past Friday, to agree to limited discovery on the jurisdictional issues. (*See* Exhibit A (DexCom letter dated September 2, 2005)). DexCom's position is contrary to law. "Ordinarily, when a defendant moves to dismiss for lack of jurisdiction, either party should be allowed discovery on the factual issues raised by that motion." *Canavan v. Beneficial Finance Corp.*, 553 F.2d 860, 865 (3d Cir. 1977) (reversing dismissal on jurisdiction grounds due to the lack of discovery on the issue); *Valentin v. Hosp. Bella Vista*, 254 F.3d 358, 363 (1st Cir. 2001) (on a Rule 12(b)(1) motion, courts have "broad authority to order discovery, consider extrinsic evidence, and hold evidentiary hearings in order to determine its own jurisdiction").

As indicated in the attached letter (Exhibit B), sent the day after receiving DexCom's motion to dismiss, Abbott is making what it believes is a reasonable request for discovery about the specific allegations that DexCom is relying upon for its Rule 12(b)(1) motion, including its assertion that the FDA may not approve its product or may require DexCom to revise its product in a way that could materially alter the infringement analysis. Based on Abbott's understanding of the current situation, these are remote and unrealistic possibilities. Thus, Abbott seeks discovery on DexCom's own assessment of those alleged possibilities, as well as the specific nature of DexCom's recent communications with the FDA.

By declining to agree to this discovery, DexCom appears to take the position that, regardless of the practical likelihood of its alleged possibilities ever occurring, discovery is unnecessary because at least a theoretical possibility will always remain that the FDA will not approve its product or require a change in the product. This argument is contrary to the law. When determining whether to exercise declaratory jurisdiction after a defendant raises such possible contingencies, courts should "focus on the practical likelihood that the contingencies

will occur." *E.R. Squibb & Sons, Inc. v. Lloyd's & Cos.*, 241 F.3d 154, 177 (2d Cir. 2001) (citing *Associated Indemnity Corp. v. Fairchild Industries, Inc.*, 961 F.2d 32 (2d Cir. 1992)); *Chevron U.S.A. Inc. v. Traillour Oil Co.*, 987 F.2d 1138, 1153 (5th Cir 1993) (same); *Seippel v. Jenkens & Gilchrist, P.C.*, 341 F. Supp. 2d 363, 383 (S.D.N.Y. 2004) (same); *Molitch v. Brotman*, No. Civ. A. 96-7742, 1997 WL 431008, at *2 (E.D.Pa. July 15, 1997) (declaratory plaintiff need not establish that the prospect of injury "is a mathematical certainty" and, instead, jurisdiction is appropriate if the threat of future injury is "real and substantial.")

This is common sense. If mere theoretical possibilities were enough to defeat declaratory jurisdiction, patent holders could never sue before the infringer actually launched its product and inflicted the damage the patentee was attempting to prevent. Yet, courts routinely entertain such declaratory judgment actions before the damage occurs and before FDA approval. *See, e.g., Glaxo Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1570-71 (Fed. Cir. 1997) ("*Novopharm*") (upholding declaratory jurisdiction where there was approximately 17 months between the complaint and actual infringement); *Glaxo Group Ltd. v. Apotex, Inc.*, 130 F. Supp. 2d 1006, 1008 (N.D. Ill. 2001) ("*Glaxo I*") (upholding declaratory jurisdiction where there was 13 to 19 months between complaint and actual infringement).

As the Federal Circuit explained, "[a] patent holder may seek a declaratory judgment that a person will infringe a patent in the future provided that there is an actual controversy that is both real and immediate." *Novopharm*, 110 F.3d at 1570-71; *Lang v. Pacific Marine & Supply Co., Ltd.*, 895 F.2d 761, 764 (Fed. Cir. 1990). An actual controversy exists in an action for future infringement if (1) the defendant is "engaged in an activity directed toward making, selling, or using subject to an infringement charge under 35 U.S.C. § 271(a), or [is] making meaningful preparation for such activity;" and (2) acts of the defendant "indicate a

refusal to change the course of its actions in the face of acts by the patentee sufficient to create a reasonable apprehension that a suit will be forthcoming." *Lang*, 895 F.2d at 764; *accord Novopharm*, 110 F.3d at 1571 (noting that "systematically attempting to meet the applicable regulatory requirements" for FDA approval indicates an intent to enter market); *Kos Pharm., Inc. v. Barr Labs, Inc.*, 242 F. Supp. 2d 311, 318 (S.D.N.Y. 2003) (holding that filing FDA application and embarking "upon a protracted and costly process of obtaining regulatory approval" demonstrates meaningful preparation sufficient to establish an actual controversy); *Glaxo I*, 130 F. Supp. 2d at 1008 (same).

Rather than focusing on the two factors set forth by the Federal Circuit, DexCom is merely alleging that the situation could possibly change if it fails to obtain FDA approval or it changes its product. But that is exactly what Abbott is seeking discovery about – the practical likelihood of these alleged possibilities ever occurring. DexCom should not be permitted to insulate its allegations from challenge by refusing relevant discovery, particularly when DexCom's motion attaches multiple documents and an affidavit in support of its allegations.

Accordingly, Abbott seeks an order compelling DexCom to produce documents relating to, and a Rule 30(b)(6) witness to testify about:

(1) DexCom's communications with the FDA since April 1, 2005, including any response, assessment, and/or internal analysis of those communications;

(2) DexCom's internal assessments on the likelihood that it will get FDA approval;

(3) DexCom's internal estimates about the projected date of approval of its product, as well as any preparations for a planned product launch; and

(4) DexCom's internal assessments on the likelihood that, under any circumstances, it will alter its product before getting FDA approval and, if so, in what manner.

As a result, Abbott requests a 45-day adjournment of the briefing schedule in order to conduct this specified discovery, with DexCom producing the relevant documents within 15 days (by

September 21, 2005) and a Rule 30(b)(6) witness or witnesses in the following 15 days (by October 6, 2005), and Abbott filing its brief within 15 days thereafter (by October 21, 2005). A proposed form of order is attached (Exhibit C).

MORRIS, NICHOLS, ARSHT & TUNNELL

/s/ Mary B. Graham

Mary B. Graham (#2256)
James W. Parrett, Jr. (#4292)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200

Attorneys for Plaintiff
Abbott Diabetes Care, Inc.

OF COUNSEL:

James F. Hurst
Stephanie S. McCallum
WINSTON & STRAWN LLP
35 West Wacker Drive
Chicago, Illinois 60601
Tele: (312) 558-5600
Fax: (312) 558-5700

Dated: September 6, 2005

481890

RULE 7.1.1. CERTIFICATION

Counsel has sought DexCom's agreement that Abbott may obtain jurisdictional discovery prior to responding to DexCom's motion, and DexCom has not agreed.

Dated: September 6, 2005

/s/ Mary B. Graham

Mary B. Graham (#2256)

481896

CERTIFICATE OF SERVICE

I hereby certify that on September 6, 2005, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF which will send electronic notification of such filing to the following:

Steven J. Balick
ASHBY & GEDDES
222 Delaware Avenue
P.O. Box 1150
Wilmington, DE 19899

Additionally, I hereby certify that true and correct copies of the foregoing were caused to be served on September 6, 2005 upon the following individuals in the manner indicated:

BY FACSIMILE

Steven J. Balick
ASHBY & GEDDES
222 Delaware Avenue
P.O. Box 1150
Wilmington, DE 19899

BY FACSIMILE

David C. Doyle
MORRISON & FOERSTER LLP
3811 Valley Centre Drive
Suite 500
San Diego, CA 92130-2332

/s/ Mary B. Graham

Mary B. Graham (#2256)